Micro Health Laboratories
.....for precious life

NIPT Test Request Form
International V-0.4

MICROGEN NIPT

PATIENT INFORMATION GENERAL*

First Name
Surname
Date of Birth | DD | MM | YYYY
Nationality
Address
Email ID
Phone No
ID No

CLINICIAN DETAILS*

Clinician Name
Hospital Name
Address
Email ID
Phone No

SAMPLE COLLECTION DETAILS*

Date of Sample Collection | DD | MM | YYYY
Sample Type ☐ Streck Tube ☐ Buccal Swab

TEST ORDERING INFORMATION*

(select ✓ one test panel below)

THIS TEST IS VALIDATED FOR PREGNANCIES OF AT LEAST 10 WEEKS GESTATIONAL AGE.

☐ **MicroGen Basic – NIPT Screening Test**

MICROGEN NIPT BASIC

- ☑ Trisomy 21,18,13
- ☑ Sex chromosome aneuploidy
- ☑ Presence of Y chromosome

Sample Type: 8-10 ml Maternal Blood in STRECK BCT tube (18~25°C)

☐ **MicroGen Premium – NIPT Screening Test**

MICROGEN NIPT PREMIUM

- ☑ All chromosome aberration
- ☑ Sex chromosome aneuploidy
- ☑ Presence of Y chromosome
- ☑ 116 Microdeletions

Sample Type: 8-10 ml Maternal Blood in STRECK BCT tube (18~25°C)

☐ **MicroGen Monogenic – NIPT Screening Test**

MICROGEN NIPT MONOGENIC

- ☑ Trisomy 21,18,13
- ☑ Sex chromosome aneuploidy
- ☑ Presence of Y chromosome
- ☑ 4 Microdeletions
- ☑ 100 Monogenic diseases
- ☑ Inclusive confirmatory test

Sample Type: 8-10 ml Maternal Blood in STRECK BCT tube (18~25°C) + 2 Buccal swab from biological father

PREGNANCY TYPE*

Regular Pregnancy	IVF Pregnancy Self Egg Used	IVF Pregnancy Donor Egg Used or Surrogate
☐ Singleton	☐ Singleton	☐ Singleton
☐ Twin#	☐ Twin#	☐ Twin#
☐ Vanishing Twins	☐ Vanishing Twins	☐ Vanishing Twins

Please refere **Table A** , turn overleaf

PREGNANCY INFORMATION*

Gestational Age* (on collection date) ☐ Wks ☐ Days
GA Calculated by ☐ LMP ☐ USG ☐ IVF
LMP* | DD | MM | YYYY
EDD* | DD | MM | YYYY

Maternal Weight* ☐ Kgs
Maternal Height* ☐ Ft.inch ☐ Cm
☐ Gravida ☐ Para ☐ Abortions
☐ Still Birth ☐ Live Issue

Consanguineous Marriage ☐ Yes ☐ No
If Yes ☐ Uncle-Niece / First Cousins
☐ More Distant
History of Infertility ☐ Yes ☐ No

First Trimester / Combined Screening (Risk Score) _____
Nuchal Translucency: NT (mm) _____ CRL (mm) _____
Triple Marker Screening (Risk Score) _____
Quadruple Screening (Risk Score) _____

Ultrasound abnormalities ☐ Yes ☐ No
Is mother a Microdeletion carrier ? ☐ Yes ☐ No
Specify Chromosomal abnormalities of Fetus (if known) _____
Family history of Chromosomal abnormality _____
Others _____

REASON FOR REFERRAL*

☐ Screening purpose ☐ Positive serum screen ☐ Prior Pregnancy risk ☐ Personal or family history of aneuploidy
☐ Advanced maternal age ☐ Abnormal ultrasound ☐ IVF (in vitro fertilization) ☐ _____

FOR LABORATORY USE ONLY

Sample Type

☐ Mother's blood in STRECK Tube Do not Freeze
_____
☐ Biological father's buccal swab Do not Freeze

Sample Received / Checked by:

Date/Time :_____

Technician Signature:_____

BARCODE STICKER/LAB ID

*accurate information is necessary for a valid interpretation | please (✓) boxes

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MICROGEN™ NIPT

TEST CRITERIA & LIMITATIONS:

Consult with your healthcare provider to determine if MicroGen is appropriate for you. Please refer to the table A, below to check your eligibility.

Table A:

	Trisomies	All Chromosome aberration	Sex Chromosome Aneuploidies	Microdeletions/ Duplications (4 or 116)	Prescence of Y Chromosome	100 Monogenic Diseases
REGULAR PREGNANCY						
Singleton	✓	✓	✓	✓	✓	✓
Twin	✓	✗	✗	✓*	✓	✓
Vanishing Twins	✓	✓	✓	✓	✓	✓
IVF PREGNANCY (Self Egg Used)						
Singleton	✓	✓	✓	✓	✓	✓
Twin	✓	✗	✗	✓*	✓	✓
Vanishing Twins	✓	✓	✓	✓	✓	✓
IVF PREGNANCY (Donor Egg Used or Surrogate)						
Singleton	✓	✓	✓	✓	✓	✗
Twin	✓	✗	✗	✗	✓	✗
Vanishing Twins	✓	✓	✓	✓	✓	✗

Note: * For Twin pregnancies:
- Testing for 4 microdeletions can be done after the 10th week of pregnancy.
- Testing of comprehensive that covers 116 microdeletions and duplications is available, **After the 12th week of pregnancy**.

***NOTE:** Gender identification can only determine the presence or absence of a Y chromosome. Its availability is subject to the regulations of the health authority in the requesting country

1. Singleton, vanishing twin, and IVF singleton pregnancies (using either the mother's own eggs, donor eggs, or a surrogate) are eligible for testing after the 10th week of gestation for all 23 autosomal chromosome aneuploidies, sex chromosome aneuploidies, and 116 microdeletions. For pregnancies resulting from vanishing twins, testing should occur four weeks after the vanishing event.
2. However, twin pregnancies after the 10th week of gestation are only eligible for testing for trisomies 21, 18, and 13, as well as selected 4 microdeletions. After the 12th week of gestation, they are eligible to undergo a comprehensive test for 116 microdeletions/duplications. However, they are not eligible for testing for sex chromosome aneuploidies.
3. MicroGen Monogenic offers testing for a selected number of pathogenic and likely pathogenic mutations associated with 100 monogenic diseases listed in the annexure (II) for singleton, twin, and vanished twin pregnancies, including in-vitro fertilization (IVF) pregnancies using the mother's own eggs, after the 10th week of gestation.

3.1 The test is available for trisomies 21, 18, and 13, as well as selected 4 microdeletions. However, it is not eligible for testing for sex chromosome aneuploidies for twin and vanished twin gestations. Testing for pregnancies resulting from vanishing twins should occur four weeks after the vanishing event.

3.2 Pregnancies achieved with egg/sperm donation or surrogacy cannot be tested with MicroGen Monogenic. Patients with malignancy or a history of malignancy, bone marrow or organ transplant, or recent transfusion are also ineligible for the test.

3.3 Samples from both biological parents are required for the test to be performed, and the test result is only valid if the samples are collected from the biological parents. In some cases, the amount of fetal DNA present in maternal blood (fetal fraction) may be insufficient for analysis (less than 4%), and a redraw may be required.

4. MicroGen is a screening test, and its positive predictive value is not 100% reliable. Therefore, confirmatory testing is necessary before making any irreversible decisions about the pregnancy. Moreover, it does not rule out the possibility of other chromosomal abnormalities, birth defects, or complications.
5. There are various factors that can lead to false positive and false negative results, including chromosomal or sub chromosomal abnormalities, birth defects such as open neural tube defects or other conditions like autism, as well as maternal, fetal, and placental mosaicism, which refer to the presence of both normal and abnormal cells in the pregnancy. Other possible sources of inaccuracy include malignancies, prior history of cancer, bone marrow or organ transplant, recent blood transfusions. In addition, false negative or false positive results can occur in cases of fetal reduction, vanishing twin syndrome, or fetal demise.
6. Test failure can happen due to the low fetal fraction (less than 4%). It is also important to note that this test does not screen for polyploidy (such as triploidy).
7. For a definitive diagnosis, chorionic villus sampling, or amniocentesis would be necessary.
8. This test processed in overseas referral laboratory that is accredited by the College of American Pathologists (CAP).

PATIENT CONSENT:

By placing my signature signing below I hereby:

1. Confirm that I have read, or have had the test description and the limitations read to me, and that I understand them.
2. I declare that I have had the opportunity to receive counseling from the referring healthcare provider regarding the MicroGen test, including its benefits, risks, and limitations, as well as the reasons for performing the test and the availability of alternative testing options, to my satisfaction
3. Authorize my referring healthcare provider to collect the necessary blood / swab samples, and to submit this form and transport the samples to MHL for the purposes of conducting the tests requested with this form.
4. Authorize MHL to communicate the results of the test to my referring healthcare provider.
5. Confirm that all the information on this form is true to the best of my knowledge.
6. By signing this form, I agree to allow MHL to use the results of this test for statistical publication purposes. However, I request that all personal information be removed and kept confidential to protect my privacy.

Patient Signature: **Date:** DD | MM | YYYY

HEALTHCARE PROVIDER ATTESTATION:

I hereby certify and undertake that:

1. The patient has been informed that the test will only test for the disorders requested on this form and has been duly and thoroughly counseled about the test. They have received all the advice necessary to provide their informed consent, including the benefits, risks, and limitations of the MicroGen NIPT test.
2. I have answered all the patient's queries about the MicroGen NIPT test.
3. This form has been completed according to the wishes and instructions of the patient.
4. I have obtained the patient's informed consent and have witnessed their signature.

Healthcare provider signature: **Date** DD | MM | YYYY

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